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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,675	03/05/2002	Andrew F. Phillips	PHL-003	8514

7590  
David P. Gordon  
65 Woods End Road  
Stamford, CT 06905

EXAMINER
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MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/090,675

Applicant(s)

PHILLIPS, ANDREW F.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8, 13-16, 19-21 and 23-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9, 10, 12, 17, 18 and 22 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's traversal of species 2 shown in fig. 8 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the species shown in fig. 8 (species 2) simply shows the IOL of fig. 3 (species 1) with the restraining element dissolved away, a later step of the method. This is found persuasive and fig. 8, which was originally designated species 2, is now grouped with species 1 (fig. 1-8).

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-6, 8, 13-16, 19-21, and 23-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

### ***Claim Objections***

Claims 9 and 10 are objected to because of the following informalities: Currently, claims 9 and 10 depend upon claim 8, which is a withdrawn claim. It is suggested to change the dependency of claims 9 and 10, from depending upon claim 8 to depend upon claim 7. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 17, 18, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Callahan et al. (USPN 6,517,577 B1). Referring to claim 1, Callahan discloses an IOL (10) comprising an optic portion (20) having a first flexibility (col.13, lines 4-10), a peripheral portion (60) having a second flexibility less than the first (col.12, lines 53-58; col.17, lines 17-18, haptics being the *support* for the optic, good strength and rigidity), and a restraining element (80, 90) provided to the peripheral portion (60) and adapted to maintain the optic (20) in a stressed state and the restraining element (80, 90) adapted to be removed.

Referring to claim 17, Callahan discloses a bag (hardened viscoelastic material) provided about the optic portion (20) wherein the peripheral portion (60) is defined by the bag (viscoelastic material) and an element (80, 90) provided about the bag (viscoelastic material, fig.9, 10).

Referring to claim 18, Callahan discloses a peripheral portion (60) including a structure (70) adapted to promote tissue attachment (col.14, lines 51-55, 63-67; col.15, lines 36-38).

Referring to claim 22, Callahan discloses a dissolvable element (viscoelastic material) upon dissolution, releases the restraining element (80, 90) from a restrained configuration (col.11, lines 20-27, 36-40; col.15, lines 10-38).

Claims 1, 7, 9, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell, Jr. (USPN 5,549,668). Referring to claim 1, O'Donnell discloses an IOL (1) comprising an optic portion (2 in fig.1 or 14 in fig.5) having a first flexibility (col.5, lines 15-17), a peripheral portion (area encircling columns 5 in fig.1 or 12, 13 in fig.5) having a second

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flexibility less than the first (col.5, lines 35-36), and a restraining element (hydrogel in fig.1 or 15 in fig.5) provided to the peripheral portion (area encircling columns 5 or 12, 13) and adapted to maintain the optic (2 or 14) in a stressed state and adapted to be removed.

Referring to claim 7, O'Donnell discloses the peripheral portion (area around 5) including a channel (column 5), wherein the restraining element (hydrogel, collagen) includes a fluid (hydrogel) placed within the channel (5), the channel including an outlet (top of column 5) having a seal (6) that prevents the fluid from escaping the channel (5), the seal (6) adapted to be opened in a non-surgically invasive manner.

Referring to claim 9, O'Donnell discloses a laser removable seal (6, col.5, lines 35-41).

Referring to claim 18, O'Donnell discloses a peripheral portion (area around 5, or haptics 12, 13) including a structure adapted to promote tissue attachment (embodiment in figure 1, tissue may attach and grow into columns, embodiment in fig.5, haptics 12 will attach to the tissue).

Referring to claim 22, O'Donnell discloses a laser removable element (6), which upon removal releases the restraining element (hydrogel) from a restrained configuration.

Claims 1, 7, 9, 10, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (USPN 5,607,472, cited by applicant in IDS). Referring to claim 1, Thompson discloses an IOL (22) comprising an optic portion (23) having a first flexibility, a peripheral portion (36) having a second flexibility less than the first (will be less flexible due to the presence of the viscoelastic material in this portion), and a restraining element (viscoelastic

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material) provided to the peripheral portion (36) and adapted to maintain the optic in a stressed state and adapted to be removed.

Referring to claim 7, Thompson discloses a peripheral portion (36) including a channel (28), the restraining element (viscoelastic material) including a fluid placed within the channel (28), the channel including an outlet (29) having a seal (32) that prevents fluid from escaping, and the seal (32) adapted to be opened in a non-surgically invasive manner.

Referring to claim 9, Thompson discloses a seal (32) comprising a material removable upon the application of laser light (col.6, lines 36-40; col.7, lines 35-40).

Referring to claim 10, Thompson discloses an outlet (29) including a tubular element (31) that extends toward the optic portion (fig.3A, 5).

Referring to claim 18, Thompson discloses a peripheral portion (36) including a structure (37, 38) adapted to promote tissue attachment.

Referring to claim 22, Thompson discloses a dissolvable or laser removable element (37, 38) upon dissolution or removal releases the restraining element from a restrained configuration.

Claims 1, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (USPN 4,693,717). Referring to claim 1, Michelson discloses an IOL (10) comprising an optic portion (18) having a first flexibility, a peripheral portion (20) having a second flexibility less than the first (20 will be less flexible because of the additional layers), and a restraining element (liquid) provided to the peripheral portion (20) and *adapted* to maintain the optic in a stressed state and *adapted* to be removed.

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Referring to claim 7, Michelson discloses a peripheral portion (20) including a channel (22) the restraining element (liquid) including a fluid placed within the channel (22), the channel including an outlet (end of 24) having a seal (col.5, lines 1-2) that prevents fluid from escaping, and the seal adapted to be opened in a non-surgically invasive manner.

Referring to claim 10, Michelson discloses an outlet (end of 24) including a tubular element (24) that extends (other end) toward the optic portion (18).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. (USPN 5,549,668). O'Donnell discloses an IOL having a peripheral portion with a channel, wherein a restraining element includes a fluid placed in the channel (see above). O'Donnell however, discloses the fluid to be a hydrogel, and not a balanced salt solution, as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a salt solution as the fluid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

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***Allowable Subject Matter***

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
Cheryl Miller

**BRUCE SNOW  
PRIMARY EXAMINER**